

WHAT IS CLAIMED IS:

1. A balloon catheter, comprising:
 - a) an elongated shaft having an inflation lumen, and a guidewire receiving lumen, and
 - 5 i) a proximal shaft section comprising a proximal tubular member having a proximal end, a distal end, and a distal portion, and defining a proximal portion of the inflation lumen;
 - ii) a distal shaft section comprising an outer tubular member having a proximal end and a distal end, and defining a distal portion of the inflation lumen, and an inner tubular member having a proximal end, a distal end, and a proximal portion in a side-by-side relationship with the distal portion of the proximal tubular member, the inner tubular member extending within the distal portion of the inflation lumen and beyond the distal end of the outer tubular member and defining the guidewire lumen in fluid communication with a guidewire distal port at a distal end of the catheter shaft and a guidewire proximal port at the proximal end of the inner tubular member; and
 - 15 iii) a polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, formed of a first polymeric material having a glass transition temperature greater than a

- RECEIVED
U.S. PATENT AND TRADEMARK OFFICE
MAY 20 2003
- glass transition temperature of a second polymeric material forming the distal portion of the proximal tubular member; and
- b) a balloon on the distal shaft section, having an interior in fluid communication with the inflation lumen.
- 5 2. The balloon catheter of claim 1 wherein the first polymeric material forming the polymeric reinforcing member is selected from the group consisting of thermoset polyimide, and thermoplastic polyimide.
- 10 3. The balloon catheter of claim 1 wherein the first polymeric material forming the polymeric reinforcing member is thermoset polyimide.
- 10 4. The balloon catheter of claim 1 wherein the glass transition temperature of the first polymeric material forming the polymeric reinforcing member is about 380° C to about 450° C.
- 15 5. The balloon catheter of claim 1 wherein the second polymeric material forming the distal portion of the proximal tubular member is selected from the group consisting of nylon, polyether block amide, polyurethane, and adhesive polymer.
- 15 6. The balloon catheter of claim 1 wherein the inner tubular member is multilayered, with an outer layer formed of the second polymeric material.

7. The balloon catheter of claim 1 wherein the polymeric reinforcing member is a multilayered tube having an inner layer formed of the first polymeric material and an outer layer formed of a third polymeric material.

8. The balloon catheter of claim 7 including a support mandrel within 5 at least a section of the inflation lumen, having a distal section secured to the outer layer of the polymeric reinforcing member.

9. The balloon catheter of claim 1 wherein the polymeric reinforcing member has a length about equal to the length of the proximal portion of the inner tubular member.

10 10. The balloon catheter of claim 1 wherein the proximal tubular member comprises a first tube, and a second tube which is distal to the first tube and which has a proximal end bonded to a distal end of a first tube, and which forms the distal portion of the proximal tubular member.

11. The balloon catheter of claim 10 wherein the proximal tubular member first tube is formed of a material selected from the group consisting of 15 a metal and a polymer.

12. The balloon catheter of claim 1 wherein the polymeric reinforcing member is on an outer surface of the proximal portion of the inner tubular member.

13. The balloon catheter of claim 12 including a support mandrel within at least a section of the inflation lumen.

14. The balloon catheter of claim 1 wherein the polymeric reinforcing member is on an inner surface of the proximal portion of the inner tubular
5 member.

15. The balloon catheter of claim 14 including a support mandrel within at least a section of the inflation lumen.

16. The balloon catheter of claim 1 wherein the polymeric reinforcing tube is on an inner surface of the distal portion of the proximal tubular
10 member.

17. The balloon catheter of claim 16 including a support mandrel within at least a section of the inflation lumen, with a distal section extending along an inner or outer surface of the polymeric reinforcing member.

18. The balloon catheter of claim 17 wherein the support mandrel
15 extends within the proximal tubular member and adjacent to the outer surface of the polymeric reinforcing member therein, and is bonded to the outer surface of the polymeric reinforcing member.

19. The catheter of claim 18, wherein the support mandrel is secured to an inner surface of the proximal tubular member

20. The balloon catheter of claim 17 wherein the support mandrel extends within the polymeric reinforcing member adjacent to the inner surface of the polymeric reinforcing member.

21. The balloon catheter of claim 17 wherein the support mandrel has
5 a distal end embedded within polymeric material of the shaft.

22. The balloon catheter of claim 17 wherein the support mandrel distal section is unsecured within the shaft, to allow for removal of the support mandrel therefrom.

23. The balloon catheter of claim 1 including a support mandrel in the
10 shaft extending adjacent to an outer or inner surface of the polymeric reinforcing member.

24. The balloon catheter of claim 23 wherein the support mandrel is about 110 to about 125 cm long.

25. The balloon catheter of claim 1 wherein the distal portion of the
15 proximal tubular member and the proximal portion of the inner tubular member are heat fused together.

26. The balloon catheter of claim 23, wherein the support mandrel is formed of a material selected from the group consisting of stainless steel, nickel titanium, polyetherether ketone, and nylon.

27. The balloon catheter of claim 1 wherein the proximal portion of the inner tubular member is parallel to the distal portion of the proximal tubular member.

28. The balloon catheter of claim 1 wherein the polymeric reinforcing member is a tube having a length of about 2 to about 10 cm.

29. The balloon catheter of claim 1 wherein the polymeric reinforcing member is a tube having a wall thickness of about 0.01 to about 0.03 mm.

30. A rapid exchange balloon catheter, comprising:

a) an elongated shaft having a proximal shaft section, a distal shaft section, an inflation lumen, and a guidewire lumen extending in the distal shaft section, and

i) a proximal tubular member having a proximal end, a distal end, and a distal portion, and defining a proximal portion of the inflation lumen;

ii) a distal outer tubular member having a proximal end, a distal end, and a proximal section secured to a distal section of the proximal tubular member, and defining a distal portion of the inflation lumen;

iii) a distal inner tubular member extending within the distal portion of the inflation lumen in the distal outer tubular member and beyond the distal end of the distal outer tubular

member, defining the guidewire lumen in fluid communication with a guidewire proximal port at the proximal end of the inner tubular member and a guidewire distal port at the distal end of the catheter, and having a proximal end, a distal end, and a proximal portion in a side-by-side relationship with the distal portion of the proximal tubular member; and

- 5 iv) a polymeric reinforcing tube around or within the proximal portion of the distal inner tubular member or the distal portion of the proximal tubular member, formed of a thermoset polyimide material; and
- 10 b) a balloon on the distal shaft section, having an interior in fluid communication with the inflation lumen.

31. The balloon catheter of claim 30 wherein the thermoset polyimide material has a glass transition temperature greater than a glass transition 15 temperature of a polymeric material forming the distal portion of the proximal tubular member

32. The balloon catheter of claim 30 wherein the thermoset polyimide material has a glass transition temperature greater than a glass transition temperature of a polymeric material forming the proximal portion of the distal 20 inner tubular member.

33. The balloon catheter of claim 30 including a support mandrel in the shaft extending adjacent to an outer or inner surface of the thermoset polyimide reinforcing member.

34. The balloon catheter of claim 30 wherein the thermoset polyimide reinforcing member is a multilayered tube with at least one layer of the thermoset polyimide.

35. The balloon catheter of claim 30 wherein the proximal portion of the inner tubular member and the distal portion of the proximal tubular member are fusion bonded together.

10 36. A method of making a balloon catheter, comprising:
 a) assembling a catheter shaft having a proximal tubular member, a distal inner tubular member at least in part within a distal outer tubular member, and a polymeric reinforcing tube around or within a proximal portion of the distal inner tubular member or a distal end of the proximal tubular member, by positioning the distal portion of the proximal tubular member in a side-by-side relationship with the proximal portion of the distal inner tubular member, the polymeric reinforcing tube being formed of a first polymeric material having a glass transition temperature greater than a glass transition temperature of a second polymeric material forming the distal portion of the proximal tubular member;

- b) heating and thermally fusing the distal portion of the proximal tubular member and the proximal portion of the distal inner tubular member together and to the distal outer tubular member; and
- 5 c) bonding a balloon to a distal end of the distal outer tubular member and to a distal end of the distal inner tubular member so that the balloon has an interior in fluid communication with a lumen of the distal outer tubular member and a lumen of the proximal tubular member.

37. A catheter, comprising an elongated shaft having a first lumen,

10 and a second lumen, and having

a) a proximal shaft section comprising a proximal tubular member having a proximal end, a distal end, and a distal portion, and defining a proximal portion of the first lumen;

15 b) a distal shaft section comprising an outer tubular member having a proximal end and a distal end, and defining a distal portion of the first lumen, and an inner tubular member having a proximal end, a distal end, and a proximal portion in a side-by-side relationship with the distal portion of the proximal tubular member, the inner tubular member extending within the distal portion of the first lumen and beyond the distal end of the outer tubular member and defining the second lumen in

20 fluid communication with a distal port at a distal end of the catheter shaft

and a proximal port at the proximal end of the inner tubular member;
and

c) a polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, formed of a first polymeric material having a glass transition temperature greater than a glass transition temperature of a second polymeric material forming the distal portion of the proximal tubular member.

38. The catheter of claim 37 wherein the first polymeric material is a

10 polyimide.

39. The catheter of claim 37 wherein the first polymeric material is a thermoset polyimide.